



# THE CLINICAL STUDY ON A MINIMAL INVASIVE TREATMENT IN THE MANAGEMENT OF MUTRAASHMARIJANYA SHOOL w.s.r. RENAL CALCULI PAIN

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## ABSTRACT

Renal calculi/calculus (Mutraashmari) is one of those ailments wherein one may have to cease all his daily duties instantaneously due to the pain. Not only that, once the calculi/calculus is formed & is not cured it keeps on giving bouts of pain, painful & burning micturition with or without hematuria. Many researches have been done in this area but the administration route being oral only. No much of the work is done in the treatment of Mutraashmari in the form of Basti (Enema). Hence an attempt to treat the Mutraashmarijany Shool by giving Matra-basti of the Varunadi tailam as mentioned in the Bhaisjya-Ratnavali. The clinical study entitled "The Clinical Study on A Minimal Invasive Treatment In The Management Of Mutraashmarijany Shoola w.s.r. Renal calculi pain", was undertaken to discern and to understand the possible mechanism of action of an Matr-Basti of the medicated oil will exhibit and achieve an analgesic effect in the pacifying the Mutraashmarijany Shool and whether will it be able to relieve the associated symptoms too. It won't be an exaggerated statement to make that, the task of taking Bastikarma in Mutraashmari especially to pacify the colicky pain as a topic for a clinical study was indeed a challenge to undertake. During this clinical study, the concept of Snehapak-kalpna, the various methods of drug standardization were implemented with the ideal ways of conducting and handling a clinical research work.

**KEYWORDS:** Mutraashmari, Renal calculi/calculus, Mutraashmarijany -Shool, Pain, Matra-basti, Varunadi Tailam.

## INTRODUCTION:

In the Indian culture right from the time of our birth we unceasingly undergo the various 'Samskaras' and the 'Charyas' as preached by our Acharyas. These Samskaras are actually meant for the natural body clock, ultimately for good health. Any attempt to breach in following these rules gives rise to diseases. This golden concept has been mentioned thousands of years back by our Acharyas. In today's time people are literally competing with the unstoppable Time and in doing so they fail to perform even small daily chores viz., micturition, defecation, oral hygiene, etc. Not taking care of the body, even if its excretory system signals (Adhameeya vega) for the expulsion of the urine and stools and suppressing the natural urges is seen on large scale in daily practice and illness is the obvious outcome to face. Suppressing micturition urge, not following Dinacharya, Ritucharya, excessive stress, intake of the various junk food & medicines causes renal system ailments. Renal calculus is one of those ailments whose pain could be at time so intense that one may have to cease all his daily duties instantaneously. Not only that, once the calculi/calculus is formed & is not cured it keeps on giving bouts of pain, painful & burning micturition with or without hematuria. Allopathy has many wonder drugs to kill the pain and associated symptoms immediately, just like the magical wand. But with all this, these drugs may also cause many side-effects ranging from hyperacidity to severe anaphylactic shock. Hence surgical intervention remains the only option in the hands of today's modern surgeons. All the Ayurvedic texts have mentioned multiple drugs compounds for the treatment of the Mutraashmari. Many researches have been done in this area but the administration route being oral only hence an attempt to treat the Mutraashmarijany Shool by giving matra-basti of the Varunadi tailam, as mentioned in the Bhaisjya Ratnavali<sup>1</sup>. It is the vitiation of the vata-dosha that gives rise to the severe pain and bastikarma<sup>2</sup> is considered the best treatment to control and pacify the vitiated vata-dosha and thereby alleviate the mutraashmarijany Shool. While going through the texts, we find that in the purvarupa & rupa of the mutraashmari snehakarma is advised<sup>3,4</sup>. Also in the Sushrut samhita it has been mentioned that the mutranirmiti (formation of the urine) takes place in the pakwashaaya<sup>5</sup>. Considering all the references the administration of the varunadi-tailam in Mutraashmari rogajany Shool in the matra-basti should yield result.

## AIMS AND OBJECTIVES:

1. To clinically assess the Shoolaghna (analgesic) properties of Varunadi Tailam Matra-Basti
2. To make an effective, cost effective, authentic, accessible conservative alternative or management of Mutraashmarijany Shool.
3. To observe and propose the possible mechanism of the action of the Varunadi-tailam Matra-Basti viz. Varuna (Crataeva nurvula), Gokshura (Tribulus terrestris) and Teel tailam (Oil of Sesamum indicum)
4. To observe the side-effects & the complications of Varunadi-tailam Matra-basti, if any.
5. To review the complete literature available on acute or chronic pain in Mutraashmari.

**Materials and methods:** The therapeutic use of Varunadi Tailam Matra-Basti in management of Mutraashmarijany Shool; this yoga (formulation) has reference from the Bhaisjya-Ratnavali. An Open uncontrolled study was conducted in the OPD & IPD; at the Shalyatantra department of the concerned Hospital, after taking clearance from its Ethical Committee. An informed written consent was taken from all 30 the pts. in the language they well understood before commencing the trial. The pts. clinically diagnosed to have renal calculi/calculus and having at least two symptoms of the following-painful micturition, burning micturition & hematuria. The exclusion & the inclusion criteria of pts. of the study are given. All routine Haematological investigations were done before starting the trial. Only TLC, DLC, RFT, Urine R. & Micro., X-ray KUB & USG-KUB were done both before and after to rule out any adverse effect of the therapy and also to see whether there was any effect on the size & number of the calculi/calculus; though a secondary finding. Following were the main criteria for the clinical assessment in this trial

- A) Local Pain
- B) Painful Micturition
- C) Burning Micturition
- D) Hematuria

To assess the improvement in symptoms of gradations on the basis of severity & duration the changes in the gradations of the symptoms indicate the effect of trial drug.

The effect of the therapy was assessed in terms of cured (100% relief), markedly improved (50-100% relief), improved (25-50% relief) and unchanged (25% to no relief).

## OBSERVATIONS & RESULTS:

The data generated during the study can be grouped under 3 headings:

- A) Chemical Analysis of the drug used: Drug standardization (authentication of drugs, various analytical tests of the ingredients & the preparations were done at known and a standard pharmaceutical laboratories) was done as per the norms and recommendations, suggested by the CCRAS, Ministry of health & family welfare, New Delhi.
- B) Demographic Analysis: Here the pts. analysed with respect to various parameters of the Demography (age, sex, religion, education, occupation, marital status, etc) in the form of tables & graphs are mentioned.
- C) Clinical efficacy of drug after completion of the therapy was shown as the % of relief observed in pts. for the particular symptoms. Also the duration of time needed to achieve the relief was shown in form of tables and by applying appropriate Statistical analysis. Wilcoxon-matched- pairs-signed-ranks test was applied to the total symptom score which was seen to highly significant.

Effect of Therapy on Investigations was statistical analyzed by applying the 't' – paired test showed insignificant effect on TLC, DLC whereas slight significant effect in normal of Mean Sr Creatinine, Sr Uric acid, BUN & BUL was seen. Thus indicating that therapy causes no adverse effects on any of the investigations. As far as Urine Routine and Microscopy is concerned, enough data was not available for the calculation of the statistics. But still the chart shows that the urine infection was corrected at the end of the treatment. X-Ray & USG KUB: - USG - KUB was done before and after the therapy as its reporting was found much more reliable than X-Ray KUB. But as the therapy was meant for relieving the pain & not much significant change was seen in the regression of size of calculi/calculus after completion of the therapy in the maximum number of pts. taken in the study hence none of the statistical tests or analysis can be made hence not mentioned.

Total Effect of therapy on 30 Patients of Mutraashmari was assessed in terms as the Patient wise percentage of relief; which showed that out of the 30 patients observed patients (73.33 %) showed 100 % relief in the symptoms & patients (26.67%) were markedly improved in the symptoms.

## DISCUSSION:

As per the Ayurvedic texts; suppression of the Mutra vega (Adharaneeya vega), not following the daily cores of life as advocated by the age-old Shastra, not abiding with the Dashavidha Aaharayatana & also not carrying out the Samshodhan kriyas (Panchkarmas) duly as per one's Prakruti, Koshta, Agni and the seasonal variations (Ritus ); all these reasons act as a nidus for the Mutraashmari Nirmiti .The etiopathogenesis of the Mutraashmari described by Ayurveda & that by the Modern texts are suggestive of similar pattern of Calculi/calculus formation.

This clinical study was selected because Shool in Mutraashmari has been noted to be an important symptom amongst the rest and hence a search for an effective weapon to tackle it is the need of the hour today. This is so, because the Allopathic analgesic drugs are notoriously known to cause adverse-effects ranging from acidity to anaphylactic shock. Not only this but a large proportion of pts. show a recurrence in Calculi/calculus formation (after taking Modern line of treatment) and such patients' lifestyle compels them to carry on taking Analgesics & Antispasmodics to relieve the pain and to combat their side-effects they have to consume other pills. The above scenario in the management of pain related to Mutraashmari aroused the necessity to find an alternative.

Shool nirmiti in the Mutraashmari is primarily attributable to the Margaavarodhajanya Vataadosha prakopa especially the Apaanyavay as the Basti is its Karyakshetra. Even the modern view encourages the above statement; the pain / colicky pain / radiating pain in the Urolithiasis occurs when the calculi/calculus tries to pass through the Ureter; burning & painful micturition, hematuria, fever are the other associated symptoms too.

Sushruta acharya, the father of the Indian Surgery; after thoroughly analysing the etiopathogenesis of the Mutraashmari has correctly advised the Snehan via Bastikarma in the Purvaroop & the Roopa of this disease. Even Bhaisjya Ratnavali opines the same & has advised many medicated Ghrutas & Tailas; Varunadi Tailam being of them.

Varunadi Tailam was selected for combating the Shool seen in the Mutraashmari via the Per-rectal route (Basti – a Panchkarma). Basti is considered as the half treatment by the Kayachikitsa pradhan granthas but it is the complete treatment of the vitiated Vataadosha, thereby pacifier of Shool; and no two opinions on that can be made. The preparation comprises of the most important drugs viz. **Varuna and Gokshura** which have been proved to be the best drugs for combating Mutraashmari, till now the route being oral only. As the compound has Tila Tailam and on account of its pharmacological qualities it was thought that the above preparation will definitely yield results even after taking per-rectal as the route of administration.

The site of Calculi/calculus seen in pts. under study were seen much more in the Kidney (U V Junction) and more in Ureter and negligible in the Bladder indicating that the symptom Shool (pain) arises in the pt. when the calculi/calculus is at the U V junction, or impacted or transversing along the Ureters. This also helps to confirm that Vataprakopa is also Margaavarodhajanya & not always Kshayaj.

The pts. under study showed local pain (100%), painful micturition (100%) as main symptoms and 26.66% showed burning micturition and 13.33% pts. showed hematuria. Thereby indicates that almost all the pts. under trial suffering from pain either local or radiating in nature indicating the incidence of calculi/calculus formation was seen more in the Kidney & Ureter. Painful micturition was seen more than burning micturition as many a times pt. in the state of agony is unable to distinguish the difference between pain and burning sensation while micturition.

On observing the efficacy of the therapy 95.51 % of the pts. with local pain, 98.04% of pts. with painful micturition & 90.32 % of pts. with burning micturition were seen to have good result of therapy as they had none of the above symptoms at the end of the therapy. The percentage pts. with hematuria (71.42%) were seen to less relived compared to the above three parameters.

The observations & results are suggestive of that no adverse effects were seen in

any of the investigations that were done. *Out of the 30 patients observed 73.33 % Patients showed 100 % relief in the symptoms, 26.67 % Patients were markedly improved in the symptoms.*

The probable cause for the above result is that the Varunadi Tailam Matra-Basti was better at pacifying the vitiated Vataadosha as it contained drugs exhibiting diuretic, analgesic, anti-inflammatory actions and as the drugs were absorbed & assimilation without undergoing digestion. The therapy in the form of Basti probably has lesser effective action on Hematuria and still lesser as Lithotriptic action.

## Probable mechanism of action of Varunadi tailam:

Pain in the Mutraashmari is totally accountable to the Marga-avarodhajanya Vata-prakopa; especially Apaanyavayadosha as the basti is its Karyakari Kshetra. The Basti- upakrama is best known to pacify the Vataprakopa especially the Apaanyavayadosha and thereby proves useful in the management of the Mutraashmari. Sushrutaacharya mentions that Snehanakarma must be done in the form of Basti, Uttarbasti, etc. in the Purvarupa & the Rupa of the Mutraashmari. Varunadi Tailam is medicated with two potent drugs like Varuna & Gokshura. Varuna has Kashaya & Tikta rasa; Ushna veerya & is Ashmaribhedak (lithotriptic) by its Prabhav. Gokshura is Snigdha, Guru, and Madhura in rasa & vipaak. Apart from being Ushaveeryatmak; Madhur, Katu, Tikta in rasa, Madhura vipaki; Teel tailam is Vyavaee & Vikashi due to which the action of the drugs incorporated in it spread fast up to the cellular level of the body & the expected action is apparent in the study conducted & is superior of all the oils extracted from the vegetable sources. The reason for selecting the per rectal route over the other routes of administering drugs is that the Ayurveda & even the Modern study show the significance of the Bastikarma.

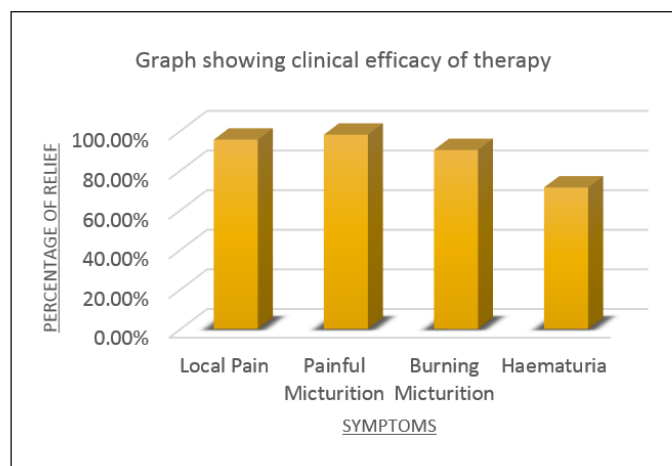
**Ayurveda:-** It has been noted to pacify the local nervous system & thereby relieve the Pain (Shool) & also does the Shodhanakarma of the body

**Modern:-** As drugs given via per rectum route are not subjected to digestion in the duodenum & hence said to maintain their nature & effect. Studies show that the absorption & assimilation of the administered medicated oil takes place without undergoing digestion.

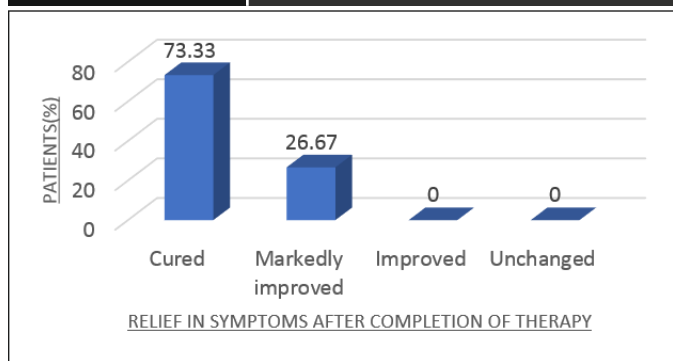
## CONCLUSION:

After conducting the clinical trial a confident conclusion can be laid down as follows:

During the trial, the review of the literature & the practical view of the study suggests a relevant relationship between the Mutraashmari & the Urinary calculi/calculus. The Anatomy & Physiology of the Mutravahastrotas described in the Ayurveda appears to be crude and also appears to have given an impetus to the Modern anatomist & physiologist to ponder upon it, which probably has given rise to today's microcellular levelled description of the Urinary System. The etiopathogenesis of the Mutraashmari & Urolithiasis appears to be very similar on giving a calm thought; especially the eg. given in Sushruta Samhita of Mrittika ghat filled with water appears to be similar to proposed stages of Calculi formation in the Renal system. The obvious differences felt during the study of both the pathies is due to the fact that these are based on fundamentals unique in their own way and seeks no denial even after thousands of years have elapsed. At the commencement of the trial there was deep sense of curiosity about how effectively will the Varunadi Tailam matrasthi will exhibit the Analgesic property especially when administered per rectally. But it is worth noting that the retrospective study did not fail even today; as the results obtained after the completion of treatment is self-explanatory.



On observing the efficacy of the therapy 95.51% of the patients with local pain, 98.04% of pts. with painful micturition & 90.32% of pts. with burning micturition were seen to have good result of therapy as they had none of the above symptoms at the end of the therapy. The percentage pts. with hematuria (71.42%) were seen to be less relieved compared to the above three parameters.



The patient wise, percentage of relief on completion of treatment is 73.33 % of pts showed 100 % relief in the symptoms, 26.67% were markedly improved in the symptoms.

The probable cause for the result is the Varunadi Tailam Matra-Basti was better at pacifying the vitiated Vatadosha as it contained drugs exhibiting diuretic, analgesic, anti-inflammatory actions as the drugs were absorbed & assimilation without undergoing digestion. The therapy probably has lesser effective action on Hematuria and still lesser as lithotriptic action.

Hence it can be concluded that the above therapy in the management of Mutraashmarijanya Shool had following achievements:

- It relieves the local pain within an hour after administration.
- It relieves the painful & burning micturition within an hour after administration.
- It also relieves hematuria to some extent.
- It doesn't cause any side-effects or adverse effects
- It serves as the cost effective & easily accessible alternative in the conservative management of the Shool of Mutraashmari.
- The therapy can be carried on OPD basis too.
- It improves the quality of life of the patient especially those with recurrence.

It can be concluded that an attempt has been made first to discern our age-old shastra and to study primarily the Shoolaghna (Analgesic) properties of Varunadi-Tailam Matra-basti in the Mutraashmari; whereas the Anti-inflammatory, Diuretic (Mutral) & Lithotriptic (ashmarighna) actions were the secondary observations & achievements to be made. Due to the sample size of 30 patients, the study results though highly encouraging, merit a more extensive evaluation & may hopefully serve as an impetus for further clinical trials on large sample size with prolonged duration of treatment in the near future. After taking all these facts into consideration it can be said that there is major advantage of this classical formulation for the patient as it allows the patient to continue his day-to-day activities & saves valuable time & renders better Quality of Life.

#### ANNEXURES:

1. Bhaishajya Ratnavali Ashmari Chikitsasthana.
2. Sushruta Samhita Chikitsasthana 7/43. Bhaishajya Ratnavali Ashmari Chikitsasthana
4. Sushruta Samhita Nidanasthana 3/21-23
5. Sushruta Samhita Chikitsasthana 35

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